IN THE UNITED STATES COURT
FOR THE DISTRICT OF DELAWARE

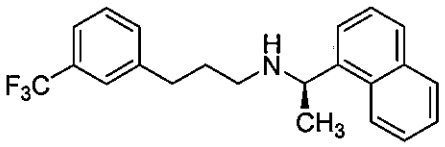
THE BRIGHAM AND WOMEN'S HOSPITAL, INC., NPS PHARMACEUTICALS, INC. and AMGEN INC.,	)	
Plaintiffs,	)	
v.	)	Civil Action No.: _____
TEVA PHARMACEUTICALS USA, INC., TEVA PHARMACEUTICAL INDUSTRIES LTD., BARR LABORATORIES, INC.,	)	
Defendants.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs The Brigham and Women's Hospital, Inc., NPS Pharmaceuticals, Inc. and Amgen Inc. (collectively "Plaintiffs") by way of Complaint against Defendants Teva Pharmaceuticals USA, Inc., Teva Pharmaceuticals Industries Ltd. and Barr Laboratories, Inc. (collectively "Defendants") allege as follows:

NATURE OF THE ACTION

1. This is an action for infringement of United States Patent No. 6,211,244 ("the '244 patent"), United States Patent No. 6,313,146 ("the '146 patent"), United States Patent No. 6,011,068 ("the '068 patent") and United States Patent No. 6,031,003 ("the '003 patent") (collectively referred to as "the Patents") arising under United States patent laws, Title 35, United States Code, § 100 *et seq.*, including 35 U.S.C. §§ 271 and 281. The Patents collectively claim, *inter alia*, cinacalcet hydrochloride as well as pharmaceutical compositions containing cinacalcet hydrochloride, and methods of treatment administering cinacalcet hydrochloride. The chemical structure for cinacalcet hydrochloride is:



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2. This action relates to Teva Pharmaceuticals USA, Inc.'s and Barr Laboratories, Inc.'s filings of Abbreviated New Drug Applications ("ANDAs") under § 505(j) of the Federal Food, Drug and Cosmetic Act ("the Act"), 21 U.S.C. § 335(j) seeking U.S. Food and Drug Administration ("FDA") approval to market a generic pharmaceutical product.

PARTIES

3. The Brigham and Women's Hospital, Inc. ("BWH") is a hospital organized and existing under the laws of the State of Massachusetts. Its principal place of business is located at 75 Francis Street, Boston, Massachusetts, 02115.

4. NPS Pharmaceuticals, Inc. ("NPS") is a corporation organized and existing under the laws of the State of Delaware. Its principal place of business is located at 550 Hills Drive, 3rd Floor, Bedminster, New Jersey 07921-1537.

5. Amgen, Inc. ("Amgen") is a corporation organized and existing under the laws of the State of Delaware. Its principal place of business is located at One Amgen Center Drive, Thousand Oaks, California 91320-1799.

6. Upon information and belief, Defendant Teva Pharmaceuticals USA, Inc. ("Teva USA") is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business located at 1090 Horsham Road, P.O.B. 1090, North Wales, Pennsylvania 19454.

7. Upon information and belief, Defendant Teva Pharmaceuticals Industries Ltd. ("Teva Ltd.") is a corporation organized under the laws of Israel, having its principal place of business located at 5 Basel Street, P.O. Box 3190, Petach Tikva 49131, Israel.

8. Upon information and belief, Defendant Teva USA is a wholly-owned subsidiary of Teva Ltd.

9. Teva USA and Teva Ltd. are hereinafter collectively referred to as "Teva."

10. Upon information and belief, Defendant Barr Laboratories, Inc. ("Barr") is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business located at 255 Summit Avenue, Montvale, New Jersey 07645.

11. The New York Times has reported that Teva Ltd. will purchase Barr and that Teva Ltd. expects the deal will close in late 2008.

JURISDICTION AND VENUE

12. This action arises under the patent laws of the United States and the Food and Drug laws of the United States, Titles 35 and 21, United States Code. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202.

13. Upon information and belief, this Court has personal jurisdiction over Teva USA. Upon information and belief, Teva USA is a corporation organized and existing under the laws of the State of Delaware. Upon information and belief, Teva USA directly, or indirectly, manufactures, markets, and sells generic drugs throughout the United States and in this judicial district. Upon information and belief, Teva USA purposefully has conducted and continues to conduct business in this judicial district, and this judicial district is a likely destination of Teva USA's generic product.

14. Upon information and belief, this Court has personal jurisdiction over Teva Ltd. Upon information and belief, Teva Ltd. is in the business of manufacturing, marketing, importing, and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Teva Ltd. directly, or through its wholly-owned subsidiaries (primarily Teva USA), conducts business within this judicial district. Upon information and belief, Teva Ltd. directly, or through its wholly-owned subsidiaries (primarily Teva USA), manufactures, markets, imports and sells generic drugs throughout the United States and in this judicial district.

15. Upon information and belief, this court has personal jurisdiction over Barr. Upon information and belief, Barr is a corporation organized and existing under the laws of the State of Delaware.

16. Venue is proper in this Court under 28 U.S.C. §§ 1391(b) and (c), and 1400(b).

FIRST CLAIM FOR RELIEF

17. Plaintiffs incorporate and reallege paragraphs 1-16 above, as if set forth specifically here.

18. United States Patent No. 6,211,244, entitled "Calcium Receptor-Active Compounds," was duly and legally issued by the United States Patent and Trademark Office ("PTO") on April 3, 2001. A copy of the '244 patent is attached hereto as Exhibit A.

19. The '244 patent is assigned to NPS and NPS is the owner of the '244 patent.

20. Amgen has been and is the exclusive licensee of the '244 patent in the United States under a "Development and License Agreement" dated March 18, 1996 between NPS and Amgen.

21. Amgen holds an approved New Drug Application ("NDA") No. 21-688 for cinacalcet hydrochloride tablets which the FDA approved on March 8, 2004.

22. Amgen sells various dosage strengths of cinacalcet hydrochloride tablets (EQ 30 mg base, EQ 60 mg base, and EQ 90 mg base) in the United States under the tradename SENSIPAR®.

23. The '244 patent is listed in Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book") for NDA No. 21-688.

24. Upon information and belief, Teva filed ANDA No. 90-539 with the FDA under the provisions of 21 U.S.C. § 355(j).

25. Upon information and belief, Teva's ANDA No. 90-539 seeks FDA approval to engage in the commercial manufacture, use, and/or sale of generic cinacalcet hydrochloride tablets, EQ 90 mg base (hereinafter "Teva's ANDA products") before the expiration of the '244 patent.

26. On or about June 12, 2008, BWH, NPS and Amgen received a letter from Teva dated June 11, 2008, purporting to be a Notice of Certification for ANDA No. 90-539 under Sections 505(j)(2)(B)(i) and (ii) of the Act, 21 U.S.C. § 355(j)(2)(B)(i) and (ii), and 21 C.F.R. § 314.95(a)-(c).

27. Teva's letter alleges that the active ingredient in Teva's ANDA products for which it seeks approval is cinacalcet hydrochloride.

28. Upon information and belief, Teva has made and included in its ANDA a Certification under 21 U.S.C. § 355(j)(2)(A)(vii)(iv) that, in its opinion and to the best of its knowledge, the '244 patent is invalid, not infringed and/or unenforceable.

29. Teva has infringed at least one claim of the '244 patent under 35 U.S.C. § 271(e)(2)(A) by filing ANDA No. 90-539 and seeking approval by the FDA to engage in the commercial manufacture, use, and/or sale of Teva's ANDA products before the expiration of the '244 patent.

30. Upon information and belief, Teva's ANDA products would, if approved and marketed, infringe the '244 patent.

31. Upon information and belief, Teva USA's actions relating to Teva USA's ANDA No. 90-539 complained of herein were done at the direction of, with the authorization of, and with the cooperation, the participation, the assistance of, and at least in part for the benefit of, Teva Ltd. and therefore, Plaintiffs are entitled to full relief from Teva Ltd.'s acts of infringement of the '244 patent under 35 U.S.C. § 271(e)(4).

SECOND CLAIM FOR RELIEF

32. Plaintiffs incorporate and reallege paragraphs 1-31 above, as if set forth specifically here.

33. United States Patent No. 6,211,244, entitled "Calcium Receptor-Active Compounds," was duly and legally issued by the United States Patent and Trademark Office ("PTO") on April 3, 2001. A copy of the '244 patent is attached hereto as Exhibit A.

34. The '244 patent is assigned to NPS and NPS is the owner of the '244 patent.

35. Amgen has been and is the exclusive licensee of the '244 patent in the United States under a "Development and License Agreement" dated March 18, 1996 between NPS and Amgen.

36. Amgen holds an approved New Drug Application ("NDA") No. 21-688 for cinacalcet hydrochloride tablets which the FDA approved on March 8, 2004.

37. Amgen sells various dosage strengths of cinacalcet hydrochloride tablets (EQ 30 mg base, EQ 60 mg base, and EQ 90 mg base) in the United States under the tradename SENSIPAR®.

38. The '244 patent is listed in Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book") for NDA No. 21-688.

39. Upon information and belief, Barr filed ANDA No. 90-476 with the FDA under the provisions of 21 U.S.C. § 355(j).

40. Upon information and belief, Barr's ANDA No. 90-476 seeks FDA approval to engage in the commercial manufacture, use, and/or sale of generic cinacalcet hydrochloride tablets, EQ 30 mg base, EQ 60 mg base, EQ 90 mg base (hereinafter "Barr's ANDA products") before the expiration of the '244 patent.

41. On or about June 16, 2008, BWH, NPS and Amgen received a letter from Barr dated June 13, 2008, purporting to be a Notice of Certification for ANDA No. 90-476 under Sections 505(j)(2)(B)(i) and (ii) of the Act, 21 U.S.C. § 355(j)(2)(B)(i) and (ii), and 21 C.F.R. § 314.95(a)-(c).

42. Barr's letter alleges that the active ingredient in Barr's ANDA products for which it seeks approval is cinacalcet hydrochloride.

43. Upon information and belief, Barr has made and included in its ANDA a Certification under 21 U.S.C. § 355(j)(2)(A)(vii)(iv) that, in its opinion and to the best of its knowledge, the '244 patent is invalid and/or not infringed.

44. Barr has infringed at least one claim of the '244 patent under 35 U.S.C. § 271(e)(2)(A) by filing ANDA No. 90-476 and seeking approval by the FDA to engage in the commercial manufacture, use, and/or sale of Barr's ANDA products before the expiration of the '244 patent.

45. Upon information and belief, Barr's ANDA products would, if approved and marketed, infringe the '244 patent.

THIRD CLAIM FOR RELIEF

46. Plaintiffs incorporate and reallege paragraphs 1-45 above, as if set forth specifically here.

47. United States Patent No. 6,313,146 ("the '146 patent"), entitled "Calcium Receptor-Active Molecules," was duly and legally issued by the PTO on November 6, 2001. A copy of the '146 patent is attached hereto as Exhibit B.

48. The '146 patent is jointly assigned to BWH and NPS, and BWH and NPS are the owners of the '146 patent.

49. Amgen has been and is the exclusive licensee of the '146 patent in the United States under the "Development and License Agreement" dated March 18, 1996 between NPS and Amgen.

50. Amgen holds an approved New Drug Application No. 21-688 for cinacalcet hydrochloride tablets which the FDA approved on March 8, 2004.

51. Amgen sells various dosage strengths of cinacalcet hydrochloride tablets (EQ 30 mg base, EQ 60 mg base, and EQ 90 mg base) in the United States under the tradename SENSIPAR®.

52. The '146 patent is listed in the Orange Book for NDA No. 21-688.

53. Upon information and belief, Teva filed ANDA No. 90-539 with the FDA under the provisions of 21 U.S.C. § 355(j).

54. Upon information and belief, Teva's ANDA No. 90-539 seeks FDA approval to engage in the commercial manufacture, use, and/or sale of generic cinacalcet hydrochloride tablets, EQ 90 mg base (hereinafter "Teva's ANDA products") before the expiration of the '146 patent.

55. On or about June 12, 2008, BWH, NPS and Amgen received a letter from Teva dated June 11, 2008, purporting to be a Notice of Certification for ANDA No. 90-539 under Sections 505(j)(2)(B)(i) and (ii) of the Act, 21 U.S.C. § 355(j)(2)(B)(i) and (ii), and 21 C.F.R. § 314.95(a)-(c).

56. Teva's letter alleges that the active ingredient in Teva's ANDA products for which it seeks approval is cinacalcet hydrochloride.

57. Upon information and belief, Teva has made and included in its ANDA a Certification under 21 U.S.C. § 355(j)(2)(A)(vii)(iv) that, in its opinion and to the best of its knowledge, the '146 patent is invalid, not infringed and/or unenforceable.

58. Teva has infringed at least one claim of the '146 patent under 35 U.S.C. § 271(e)(2)(A) by filing ANDA No. 90-539 and seeking approval by the FDA to engage in the commercial manufacture, use, and/or sale of Teva's ANDA products before the expiration of the '146 patent.

59. Upon information and belief, Teva's ANDA products would, if approved and marketed, infringe the '146 patent.

60. Upon information and belief, Teva USA's actions relating to Teva USA's ANDA No. 90-539 complained of herein were done at the direction of, with the authorization of, and with the cooperation, the participation, the assistance of, and at least in part for the benefit of, Teva Ltd. and therefore, Plaintiffs are entitled to full relief from Teva Ltd.'s acts of infringement of the '146 patent under 35 U.S.C. § 271(e)(4).

FOURTH CLAIM FOR RELIEF

61. Plaintiffs incorporate and reallege paragraphs 1-60 above, as if set forth specifically here.

62. United States Patent No. 6,313,146 ("the '146 patent"), entitled "Calcium Receptor-Active Molecules," was duly and legally issued by the PTO on November 6, 2001. A copy of the '146 patent is attached hereto as Exhibit B.

63. The '146 patent is jointly assigned to BWH and NPS, and BWH and NPS are the owners of the '146 patent.

64. Amgen has been and is the exclusive licensee of the '146 patent in the United States under the "Development and License Agreement" dated March 18, 1996 between NPS and Amgen.

65. Amgen holds an approved New Drug Application No. 21-688 for cinacalcet hydrochloride tablets which the FDA approved on March 8, 2004.

66. Amgen sells various dosage strengths of cinacalcet hydrochloride tablets (EQ 30 mg base, EQ 60 mg base, and EQ 90 mg base) in the United States under the tradename SENSIPAR®.

67. The '146 patent is listed in the Orange Book for NDA No. 21-688.

68. Upon information and belief, Barr filed ANDA No. 90-476 with the FDA under the provisions of 21 U.S.C. § 355(j).

69. Upon information and belief, Barr's ANDA No. 90-476 seeks FDA approval to engage in the commercial manufacture, use, and/or sale of generic cinacalcet hydrochloride tablets, EQ 30 mg base, EQ 60 mg base, EQ 90 mg base (hereinafter "Barr's ANDA products") before the expiration of the '146 patent.

70. On or about June 16, 2008, BWH, NPS and Amgen received a letter from Barr dated June 13, 2008, purporting to be a Notice of Certification for ANDA No. 90-476 under Sections 505(j)(2)(B)(i) and (ii) of the Act, 21 U.S.C. § 355(j)(2)(B)(i) and (ii), and 21 C.F.R. § 314.95(a)-(c).

71. Barr's letter alleges that the active ingredient in Barr's ANDA products for which it seeks approval is cinacalcet hydrochloride.

72. Upon information and belief, Barr has made and included in its ANDA a Certification under 21 U.S.C. § 355(j)(2)(A)(vii)(iv) that, in its opinion and to the best of its knowledge, the '146 patent is invalid and/or not infringed.

73. Barr has infringed at least one claim of the '146 patent under 35 U.S.C. § 271(e)(2)(A) by filing ANDA No. 90-476 and seeking approval by the FDA to engage in the commercial manufacture, use, and/or sale of Barr's ANDA products before the expiration of the '146 patent.

74. Upon information and belief, Barr's ANDA products would, if approved and marketed, infringe the '146 patent.

FIFTH CLAIM FOR RELIEF

75. Plaintiffs incorporate and reallege paragraphs 1-74 above, as if set forth specifically here.

76. United States Patent No. 6,011,068 ("the '068 patent"), entitled "Calcium Receptor-Active Molecules," was duly and legally issued by the PTO on January 4, 2000. A copy of the '068 patent is attached hereto as Exhibit C.

77. The '068 patent is jointly assigned to BWH and NPS, and BWH and NPS are the owners of the '068 patent.

78. Amgen has been and is the exclusive licensee of the '068 patent in the United States under the "Development and License Agreement" dated March 18, 1996 between NPS and Amgen.

79. Amgen holds an approved New Drug Application No. 21-688 for cinacalcet hydrochloride tablets which the FDA approved on March 8, 2004.

80. Amgen sells various dosage strengths of cinacalcet hydrochloride tablets (EQ 30 mg base, EQ 60 mg base, and EQ 90 mg base) in the United States under the tradename SENSIPAR®.

81. The '068 patent is listed in the Orange Book for NDA No. 21-688.

82. Upon information and belief, Teva filed ANDA No. 90-539 with the FDA under the provisions of 21 U.S.C. § 355(j).

83. Upon information and belief, Teva's ANDA No. 90-539 seeks FDA approval to engage in the commercial manufacture, use, and/or sale of generic cinacalcet hydrochloride tablets, EQ 90 mg base (hereinafter "Teva's ANDA products") before the expiration of the '068 patent.

84. On or about June 12, 2008, BWH, NPS and Amgen received a letter from Teva dated June 11, 2008, purporting to be a Notice of Certification for ANDA No. 90-539 under Sections 505(j)(2)(B)(i) and (ii) of the Act, 21 U.S.C. § 355(j)(2)(B)(i) and (ii), and 21 C.F.R. § 314.95(a)-(c).

85. Teva's letter alleges that the active ingredient in Teva's ANDA products for which it seeks approval is cinacalcet hydrochloride.

86. Upon information and belief, Teva has made and included in its ANDA a Certification under 21 U.S.C. § 355(j)(2)(A)(vii)(iv) that, in its opinion and to the best of its knowledge, the '068 patent is invalid, not infringed and/or unenforceable.

87. Teva has infringed at least one claim of the '068 patent under 35 U.S.C. § 271(e)(2)(A) by filing ANDA No. 90-539 and seeking approval by the FDA to engage in the commercial manufacture, use, and/or sale of Teva's ANDA products before the expiration of the '068 patent.

88. Upon information and belief, Teva's ANDA products would, if approved and marketed, infringe the '068 patent.

89. Upon information and belief, Teva USA's actions relating to Teva USA's ANDA No. 90-539 complained of herein were done at the direction of, with the authorization of, and with the cooperation, the participation, the assistance of, and at least in part for the benefit of, Teva Ltd. and therefore, Plaintiffs are entitled to full relief from Teva Ltd.'s acts of infringement of the '068 patent under 35 U.S.C. § 271(e)(4).

SIXTH CLAIM FOR RELIEF

90. Plaintiffs incorporate and reallege paragraphs 1-89 above, as if set forth specifically here.

91. United States Patent No. 6,011,068 ("the '068 patent"), entitled "Calcium Receptor-Active Molecules," was duly and legally issued by the PTO on January 4, 2000. A copy of the '068 patent is attached hereto as Exhibit C.

92. The '068 patent is jointly assigned to BWH and NPS, and BWH and NPS are the owners of the '068 patent.

93. Amgen has been and is the exclusive licensee of the '068 patent in the United States under the "Development and License Agreement" dated March 18, 1996 between NPS and Amgen.

94. Amgen holds an approved New Drug Application No. 21-688 for cinacalcet hydrochloride tablets which the FDA approved on March 8, 2004.

95. Amgen sells various dosage strengths of cinacalcet hydrochloride tablets (EQ 30 mg base, EQ 60 mg base, and EQ 90 mg base) in the United States under the tradename SENSIPAR®.

96. The '068 patent is listed in the Orange Book for NDA No. 21-688.

97. Upon information and belief, Barr filed ANDA No. 90-476 with the FDA under the provisions of 21 U.S.C. § 355(j).

98. Upon information and belief, Barr's ANDA No. 90-476 seeks FDA approval to engage in the commercial manufacture, use, and/or sale of generic cinacalcet hydrochloride tablets, EQ 30 mg base, EQ 60 mg base, EQ 90 mg base (hereinafter "Barr's ANDA products") before the expiration of the '068 patent.

99. On or about June 16, 2008, BWH, NPS and Amgen received a letter from Barr dated June 13, 2008, purporting to be a Notice of Certification for ANDA No. 90-476 under

Sections 505(j)(2)(B)(i) and (ii) of the Act, 21 U.S.C. § 355(j)(2)(B)(i) and (ii), and 21 C.F.R. § 314.95(a)-(c).

100. Barr's letter alleges that the active ingredient in Barr's ANDA products for which it seeks approval is cinacalcet hydrochloride.

101. Upon information and belief, Barr has made and included in its ANDA a Certification under 21 U.S.C. § 355(j)(2)(A)(vii)(iv) that, in its opinion and to the best of its knowledge, the '068 patent is invalid and/or not infringed.

102. Barr has infringed at least one claim of the '068 patent under 35 U.S.C. § 271(e)(2)(A) by filing ANDA No. 90-476 and seeking approval by the FDA to engage in the commercial manufacture, use, and/or sale of Barr's ANDA products before the expiration of the '068 patent.

103. Upon information and belief, Barr's ANDA products would, if approved and marketed, infringe the '068 patent.

SEVENTH CLAIM FOR RELIEF

104. Plaintiffs incorporate and reallege paragraphs 1-103 above, as if set forth specifically here.

105. United States Patent No. 6,031,003 ("the '003 patent"), entitled "Calcium Receptor-Active Molecules," was duly and legally issued by the PTO on February 29, 2000. A copy of the '003 patent is attached hereto as Exhibit D.

106. The '003 patent is jointly assigned to BWH and NPS, and BWH and NPS are the owners of the '003 patent.

107. Amgen has been and is the exclusive licensee of the '003 patent for certain compounds and in certain fields of use in the United States under the "Development and License Agreement" dated March 18, 1996 between NPS and Amgen.

108. Amgen holds an approved New Drug Application No. 21-688 for cinacalcet hydrochloride tablets which the FDA approved on March 8, 2004.

109. Amgen sells various dosage strengths of cinacalcet hydrochloride tablets (EQ 30 mg base, EQ 60 mg base, and EQ 90 mg base) in the United States under the tradename SENSIPAR®.

110. The '003 patent is listed in the Orange Book for NDA No. 21-688.

111. Upon information and belief, Teva filed ANDA No. 90-539 with the FDA under the provisions of 21 U.S.C. § 355(j).

112. Upon information and belief, Teva's ANDA No. 90-539 seeks FDA approval to engage in the commercial manufacture, use, and/or sale of generic cinacalcet hydrochloride tablets, EQ 90 mg base (hereinafter "Teva's ANDA products") before the expiration of the '003 patent.

113. On or about June 12, 2008, BWH, NPS and Amgen received a letter from Teva dated June 11, 2008, purporting to be a Notice of Certification for ANDA No. 90-539 under Sections 505(j)(2)(B)(i) and (ii) of the Act, 21 U.S.C. § 355(j)(2)(B)(i) and (ii), and 21 C.F.R. § 314.95(a)-(c).

114. Teva's letter alleges that the active ingredient in Teva's ANDA products for which it seeks approval is cinacalcet hydrochloride.

115. Upon information and belief, Teva has made and included in its ANDA a Certification under 21 U.S.C. § 355(j)(2)(A)(vii)(iv) that, in its opinion and to the best of its knowledge, the '003 patent is invalid, not infringed and/or unenforceable.

116. Teva has infringed at least one claim of the '003 patent under 35 U.S.C. § 271(e)(2)(A) by filing ANDA No. 90-539 and seeking approval by the FDA to engage in the commercial manufacture, use, and/or sale of Teva's ANDA products before the expiration of the '003 patent.

117. Upon information and belief, Teva's ANDA products would, if approved and marketed, infringe the '003 patent.

118. Upon information and belief, Teva USA's actions relating to Teva USA's ANDA No. 90-539 complained of herein were done at the direction of, with the authorization of, and with the cooperation, the participation, the assistance of, and at least in part for the benefit of, Teva Ltd. and therefore, Plaintiffs are entitled to full relief from Teva Ltd.'s acts of infringement of the '003 patent under 35 U.S.C. § 271(e)(4).

EIGHTH CLAIM FOR RELIEF

119. Plaintiffs incorporate and reallege paragraphs 1-118 above, as if set forth specifically here.

120. United States Patent No. 6,031,003 ("the '003 patent"), entitled "Calcium Receptor-Active Molecules," was duly and legally issued by the PTO on February 29, 2000. A copy of the '003 patent is attached hereto as Exhibit D.

121. The '003 patent is jointly assigned to BWH and NPS, and BWH and NPS are the owners of the '003 patent.

122. Amgen has been and is the exclusive licensee of the '003 patent for certain compounds and in certain fields of use in the United States under the "Development and License Agreement" dated March 18, 1996 between NPS and Amgen.

123. Amgen holds an approved New Drug Application No. 21-688 for cinacalcet hydrochloride tablets which the FDA approved on March 8, 2004.

124. Amgen sells various dosage strengths of cinacalcet hydrochloride tablets (EQ 30 mg base, EQ 60 mg base, and EQ 90 mg base) in the United States under the tradename SENSIPAR®.

125. The '003 patent is listed in the Orange Book for NDA No. 21-688.

126. Upon information and belief, Barr filed ANDA No. 90-476 with the FDA under the provisions of 21 U.S.C. § 355(j).

127. Upon information and belief, Barr's ANDA No. 90-476 seeks FDA approval to engage in the commercial manufacture, use, and/or sale of generic cinacalcet hydrochloride tablets, EQ 30 mg base, EQ 60 mg base, EQ 90 mg base (hereinafter "Barr's ANDA products") before the expiration of the '003 patent.

128. On or about June 16, 2008, BWH, NPS and Amgen received a letter from Barr dated June 13, 2008, purporting to be a Notice of Certification for ANDA No. 90-476 under Sections 505(j)(2)(B)(i) and (ii) of the Act, 21 U.S.C. § 355(j)(2)(B)(i) and (ii), and 21 C.F.R. § 314.95(a)-(c).

129. Barr's letter alleges that the active ingredient in Barr's ANDA products for which it seeks approval is cinacalcet hydrochloride.

130. Upon information and belief, Barr has made and included in its ANDA a Certification under 21 U.S.C. § 355(j)(2)(A)(vii)(iv) that, in its opinion and to the best of its knowledge, the '003 patent is invalid and/or not infringed.

131. Barr has infringed at least one claim of the '003 patent under 35 U.S.C. § 271(e)(2)(A) by filing ANDA No. 90-476 and seeking approval by the FDA to engage in the commercial manufacture, use, and/or sale of Barr's ANDA products before the expiration of the '003 patent.

132. Upon information and belief, Barr's ANDA products would, if approved and marketed, infringe the '003 patent.

NINTH CLAIM FOR RELIEF

133. Plaintiffs incorporate and reallege paragraphs 1-132 above, as if set forth specifically here.

134. Upon information and belief, Teva has made substantial preparations to sell Teva's ANDA products.

135. Upon information and belief, Teva intends to commence sale of Teva's ANDA products immediately upon receiving approval from the FDA.

136. The manufacture, importation, sale, and offer for sale of Teva's ANDA products, once approved by the FDA, will directly infringe, induce an/or contribute to the infringement of one or more claims of the '244 patent under 35 U.S.C. § 271(a), (b) and (c).

137. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are enjoined by this Court. Plaintiffs have no adequate remedy at law.

138. An actual controversy exists relating to Teva's threatened infringement of the '244 patent.

TENTH CLAIM FOR RELIEF

139. Plaintiffs incorporate and reallege paragraphs 1-138 above, as if set forth specifically here.

140. Upon information and belief, Barr has made substantial preparations to sell Barr's ANDA products.

141. Upon information and belief, Barr intends to commence sale of Barr's ANDA products immediately upon receiving approval from the FDA.

142. The manufacture, importation, sale, and offer for sale of Barr's ANDA products, once approved by the FDA, will directly infringe, induce an/or contribute to the infringement of one or more claims of the '244 patent under 35 U.S.C. § 271(a), (b) and (c).

143. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are enjoined by this Court. Plaintiffs have no adequate remedy at law.

144. An actual controversy exists relating to Barr's threatened infringement of the '244 patent.

ELEVENTH CLAIM FOR RELIEF

145. Plaintiffs incorporate and reallege paragraphs 1-144 above, as if set forth specifically here.

146. Upon information and belief, Teva has made substantial preparations to sell Teva's ANDA products.

147. Upon information and belief, Teva intends to commence sale of Teva's ANDA products immediately upon receiving approval from the FDA.

148. The manufacture, importation, sale, and offer for sale of Teva's ANDA products, once approved by the FDA, will directly infringe, induce an/or contribute to the infringement of one or more claims of the '146 patent under 35 U.S.C. § 271(a), (b) and (c).

149. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are enjoined by this Court. Plaintiffs have no adequate remedy at law.

150. An actual controversy exists relating to Teva's threatened infringement of the '146 patent.

TWELFTH CLAIM FOR RELIEF

151. Plaintiffs incorporate and reallege paragraphs 1-150 above, as if set forth specifically here.

152. Upon information and belief, Barr has made substantial preparations to sell Barr's ANDA products.

153. Upon information and belief, Barr intends to commence sale of Barr's ANDA products immediately upon receiving approval from the FDA.

154. The manufacture, importation, sale, and offer for sale of Barr's ANDA products, once approved by the FDA, will directly infringe, induce an/or contribute to the infringement of one or more claims of the '146 patent under 35 U.S.C. § 271(a), (b) and (c).

155. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are enjoined by this Court. Plaintiffs have no adequate remedy at law.

156. An actual controversy exists relating to Barr's threatened infringement of the '146 patent.

THIRTEENTH CLAIM FOR RELIEF

157. Plaintiffs incorporate and reallege paragraphs 1-156 above, as if set forth specifically here.

158. Upon information and belief, Teva has made substantial preparations to sell Teva's ANDA products.

159. Upon information and belief, Teva intends to commence sale of Teva's ANDA products immediately upon receiving approval from the FDA.

160. The manufacture, importation, sale, and offer for sale of Teva's ANDA products, once approved by the FDA, will directly infringe, induce an/or contribute to the infringement of one or more claims of the '068 patent under 35 U.S.C. § 271(a), (b) and (c).

161. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are enjoined by this Court. Plaintiffs have no adequate remedy at law.

162. An actual controversy exists relating to Teva's threatened infringement of the '068 patent.

FOURTEENTH CLAIM FOR RELIEF

163. Plaintiffs incorporate and reallege paragraphs 1-162 above, as if set forth specifically here.

164. Upon information and belief, Barr has made substantial preparations to sell Barr's ANDA products.

165. Upon information and belief, Barr intends to commence sale of Barr's ANDA products immediately upon receiving approval from the FDA.

166. The manufacture, importation, sale, and offer for sale of Barr's ANDA products, once approved by the FDA, will directly infringe, induce an/or contribute to the infringement of one or more claims of the '068 patent under 35 U.S.C. § 271(a), (b) and (c).

167. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are enjoined by this Court. Plaintiffs have no adequate remedy at law.

168. An actual controversy exists relating to Barr's threatened infringement of the '068 patent.

FIFTEENTH CLAIM FOR RELIEF

169. Plaintiffs incorporate and reallege paragraphs 1-168 above, as if set forth specifically here.

170. Upon information and belief, Teva has made substantial preparations to sell Teva's ANDA products.

171. Upon information and belief, Teva intends to commence sale of Teva's ANDA products immediately upon receiving approval from the FDA.

172. The manufacture, importation, sale, and offer for sale of Teva's ANDA products, once approved by the FDA, will directly infringe, induce an/or contribute to the infringement of one or more claims of the '003 patent under 35 U.S.C. § 271(a), (b) and (c).

173. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are enjoined by this Court. Plaintiffs have no adequate remedy at law.

174. An actual controversy exists relating to Teva's threatened infringement of the '003 patent.

SIXTEENTH CLAIM FOR RELIEF

175. Plaintiffs incorporate and reallege paragraphs 1-174 above, as if set forth specifically here.

176. Upon information and belief, Barr has made substantial preparations to sell Barr's ANDA products.

177. Upon information and belief, Barr intends to commence sale of Barr's ANDA products immediately upon receiving approval from the FDA.

178. The manufacture, importation, sale, and offer for sale of Barr's ANDA products, once approved by the FDA, will directly infringe, induce an/or contribute to the infringement of one or more claims of the '003 patent under 35 U.S.C. § 271(a), (b) and (c).

179. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are enjoined by this Court. Plaintiffs have no adequate remedy at law.

180. An actual controversy exists relating to Barr's threatened infringement of the '003 patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs BWH, NPS and Amgen respectfully request that the Court enter judgment in its favor and against Defendants Teva USA, Teva Ltd., and Barr on the patent infringement claim set forth above and respectfully request that this Court:

A. enter judgment that, under 35 U.S.C. § 271(e)(2)(A), Teva has infringed at least one claim of the '244 patent through submission of Teva USA's ANDA No. 90-539 to the

FDA to obtain approval for the commercial manufacture, use, import, offer for sale and/or sale in the United States of generic cinacalcet hydrochloride tablets before expiration of the '244 patent;

B. declare that the manufacture, use, offering for sale, or sale of Teva's ANDA products within the United States or importing Teva's ANDA products into the United States before the expiration of the '244 patent will infringe the '244 patent;

C. enter judgment that under 35 U.S.C. § 271(e)(2)(A), Barr has infringed at least one claim of the '244 patent through submission of Barr's ANDA No. 90-476 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale and/or sale in the United States of generic cinacalcet hydrochloride tablets before expiration of the '244 patent;

D. declare that the manufacture, use, offering for sale, or sale of Barr's ANDA products within the United States or importing Barr's ANDA products into the United States before the expiration of the '244 patent will infringe the '244 patent;

E. order that the effective date of any approval by the FDA of Defendants' generic cinacalcet hydrochloride tablets be a date that is not earlier than the expiration of the '244 patent, or any later date of exclusivity to which Plaintiffs are or become entitled, or any such later date as the Court may determine;

F. enjoin Defendants from the commercial manufacture, use, import, offer for sale and/or sale of Defendants' generic cinacalcet hydrochloride tablets until the expiration of the '244 patent, or any later date of exclusivity to which Plaintiffs are or become entitled, or any such later date as the Court may determine;

G. enjoin Defendants and all persons acting in concert with Defendants, from seeking, obtaining or maintaining approval of any ANDA until the expiration of the '244 patent,

or any later date of exclusivity to which Plaintiffs are or become entitled, or any such later date as the Court may determine;

H. enter judgment that, under 35 U.S.C. § 271(e)(2)(A), Teva has infringed at least one claim of the '146 patent through submission of Teva USA's ANDA No. 90-539 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale and/or sale in the United States of generic cinacalcet hydrochloride tablets before expiration of the '146 patent;

I. declare that the manufacture, use, offering for sale, or sale of Teva's ANDA products within the United States or importing Teva's ANDA products into the United States before the expiration of the '146 patent will infringe the '146 patent;

J. enter judgment that under 35 U.S.C. § 271(e)(2)(A), Barr has infringed at least one claim of the '146 patent through submission of Barr's ANDA No. 90-476 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale and/or sale in the United States of generic cinacalcet hydrochloride tablets before expiration of the '146 patent;

K. declare that the manufacture, use, offering for sale, or sale of Barr's ANDA products within the United States or importing Barr's ANDA products into the United States before the expiration of the '146 patent will infringe the '146 patent;

L. order that the effective date of any approval by the FDA of Defendants' generic cinacalcet hydrochloride tablets be a date that is not earlier than the expiration of the '146 patent, or any later date of exclusivity to which Plaintiffs are or become entitled, or any such later date as the Court may determine;

M. enjoin Defendants from the commercial manufacture, use, import, offer for sale and/or sale of Defendants' generic cinacalcet hydrochloride tablets until the expiration of

the '146 patent, or any later date of exclusivity to which Plaintiffs are or become entitled, or any such later date as the Court may determine;

N. enjoin Defendants and all persons acting in concert with Defendants, from seeking, obtaining or maintaining approval of any ANDA until the expiration of the '146 patent, or any later date of exclusivity to which Plaintiffs are or become entitled, or any such later date as the Court may determine;

O. enter judgment that, under 35 U.S.C. § 271(e)(2)(A), Teva has infringed at least one claim of the '068 patent through submission of Teva USA's ANDA No. 90-539 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale and/or sale in the United States of generic cinacalcet hydrochloride tablets before expiration of the '068 patent;

P. declare that the manufacture, use, offering for sale, or sale of Teva's ANDA products within the United States or importing Teva's ANDA products into the United States before the expiration of the '068 patent will infringe the '068 patent;

Q. enter judgment that under 35 U.S.C. § 271(e)(2)(A), Barr has infringed at least one claim of the '068 patent through submission of Barr's ANDA No. 90-476 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale and/or sale in the United States of generic cinacalcet hydrochloride tablets before expiration of the '068 patent;

R. declare that the manufacture, use, offering for sale, or sale of Barr's ANDA products within the United States or importing Barr's ANDA products into the United States before the expiration of the '068 patent will infringe the '068 patent;

S. order that the effective date of any approval by the FDA of Defendants' generic cinacalcet hydrochloride tablets be a date that is not earlier than the expiration of the

'068 patent, or any later date of exclusivity to which Plaintiffs are or become entitled, or any such later date as the Court may determine;

T. enjoin Defendants from the commercial manufacture, use, import, offer for sale and/or sale of Defendants' generic cinacalcet hydrochloride tablets until the expiration of the '068 patent, or any later date of exclusivity to which Plaintiffs are or become entitled, or any such later date as the Court may determine;

U. enjoin Defendants and all persons acting in concert with Defendants, from seeking, obtaining or maintaining approval of any ANDA until the expiration of the '068 patent, or any later date of exclusivity to which Plaintiffs are or become entitled, or any such later date as the Court may determine;

V. enter judgment that, under 35 U.S.C. § 271(e)(2)(A), Teva has infringed at least one claim of the '003 patent through submission of Teva USA's ANDA No. 90-539 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale and/or sale in the United States of generic cinacalcet hydrochloride tablets before expiration of the '003 patent;

W. declare that the manufacture, use, offering for sale, or sale of Teva's ANDA products within the United States or importing Teva's ANDA products into the United States before the expiration of the '003 patent will infringe the '003 patent;

X. enter judgment that under 35 U.S.C. § 271(e)(2)(A), Barr has infringed at least one claim of the '003 patent through submission of Barr's ANDA No. 90-476 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale and/or sale in the United States of generic cinacalcet hydrochloride tablets before expiration of the '003 patent;

Y. declare that the manufacture, use, offering for sale, or sale of Barr's ANDA products within the United States or importing Barr's ANDA products into the United States before the expiration of the '003 patent will infringe the '003 patent;

Z. order that the effective date of any approval by the FDA of Defendants' generic cinacalcet hydrochloride tablets be a date that is not earlier than the expiration of the '003 patent, or any later date of exclusivity to which Plaintiffs are or become entitled, or any such later date as the Court may determine;

AA. enjoin Defendants from the commercial manufacture, use, import, offer for sale and/or sale of Defendants' generic cinacalcet hydrochloride tablets until the expiration of the '003 patent, or any later date of exclusivity to which Plaintiffs are or become entitled, or any such later date as the Court may determine;

BB. enjoin Defendants and all persons acting in concert with Defendants, from seeking, obtaining or maintaining approval of any ANDA until the expiration of the '003 patent, or any later date of exclusivity to which Plaintiffs are or become entitled, or any such later date as the Court may determine;

CC. declare this to be an exceptional case under 35 U.S.C. §§ 285 and 271(e)(4) and award Plaintiffs costs, expenses and disbursements in this action, including reasonable attorney fees; and

DD. award Plaintiffs such further and additional relief as this Court deems just and proper.

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